Vaccines and the Law 101: Overview of Federal Issues in Vaccines

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FDA Role in Vaccines

- Public Health Service Act Section 351
- Not Federal Food, Drug and Cosmetic Act
- Center for Biologics Evaluation and Research (CBER) evaluates
- Process of developing vaccines takes years, and is expensive
- Animal studies for safety; Phase 1 human trials for safety (months); Phase 2 trials for safety and preliminary effectiveness (several hundred people; months to 2 years); Phase 3 trials (several hundred to thousands of people; months to years). Licenses needed for both product and establishment.
- FDA may refer new vaccine data to FDA advisory committee, Vaccine and Related Biological Products Advisory Committee (VRBPAC) for opinion

Vaccine Adverse Event Monitoring

- FDA and CDC maintain the VAERS (Vaccine Adverse Event Reporting System), as required by National Childhood Vaccine Injury Act of 1986
  - Health care providers required to report events from a government-established reportable events table, as well as contraindications for further dosing; 1-800-822-7967
  - Anyone can report adverse event of any kind occurring after administration of vaccine
- Vaccine Safety Datalink
  - CDC program with 7 HMOs (6 million patients) to report vaccine events; established in 1990

Vaccine Committees

- Advisory Committee on Immunization Practices (ACIP)
  - Establishes recommendations re: FDA-approved vaccine, including: age of administration; dosing regimen; who should receive; contraindications
  - Recommendations usually adopted by CDC
  - CDC recommendations on childhood vaccines usually adopted by states
  - States often make these recommendations mandatory for entrance to school
  - 48 states allow religious exemptions; 15 allow philosophical exemptions (NB: cases of pertussis, diptheria, measles and meningitis from haemophilus influenzae B have declined 96-100% after development and adoption of the corresponding vaccines)
- National Vaccine Advisory Committee (NVAC)
  - Advises National Vaccine Program Office on vaccine supply issues, research priorities
- Advisory Commission on Childhood Vaccines
  - Advises HHS Secretary on Vaccine Injury Compensation Program
- VRBPAC

Problems for Vaccine Development

- R&D costs; high fixed costs in general; shelf life of biologicals
- Expectation by Public of Vaccine Cost
- Size of Vaccine Market
  - Public Concerns about Vaccines
  - Free Rider Problem: Parents Choose Not to Vaccinate Children
  - Orphan Drug Program at FDA
  - Reimbursement of Physicians
    - Medicare now gives doctor an average of $18 for administration of flu shot
  - Perception (or lack thereof) by Public of Risk of Disease
- Liability Concerns
- Manufacturing Base

Direct Support for Vaccines

- OPHS: National Vaccine Program Office
- NIH: Grants for Vaccine Development, Orphan and Otherwise
- CDC:
  - Vaccines for Children Program
    - Provides state, local and territorial health agencies with money for vaccines for children who are uninsured, Medicaid recipients, American Indians and Alaska Natives and certain others
    - Provides 40% of common childhood vaccines; $977 million in 2004
    - Working towards 6 month stockpile of all pediatric vaccines
  - National Immunization Program
    - Assists state and local health departments in implementing immunization programs
    - Supports vaccine supply contracts for vaccine distribution to state and local immunization programs
    - Assess vaccination levels in state and local areas
    - Supports national surveillance of designated diseases for which effective immunizations are available

Vaccine Injury Compensation Act

- Established by National Childhood Vaccine Injury Act in 1986 in response to virtual disappearance of DTP vaccine in US because of lawsuits
- Establishes no-fault alternative to litigation for common side effects of childhood vaccines
  - Vaccine Injury Compensation Fund, funded by vaccine tax
  - Table of Injuries developed for each vaccine
  - Injuries from common vaccines have declined
- Covers adults or children who receive childhood vaccines
- Claimants may reject settlement from Vaccine Injury Compensation Fund and pursue litigation

Seasonal Influenza Vaccine

- Seasonal flu vaccine:
  - New vaccine made every year, based on available info on circulating viruses
  - WHO, CDC as collaborator and others work each year to decide elements of seasonal flu vaccine
  - Several months' notice needed to develop vaccine; recommendations for next season released in February
  - FDA makes final decision for US on vaccine composition
  - Seasonal flu vaccine in US is trivalent
  - Flu vaccine is egg-based, not cell-based
  - Seasons in Northern and Southern Hemispheres mean manufacturers are not always available to supplement Northern Hemisphere vaccine capacity. Some manufacturers are using off-season capacity for pre-pandemic flu vaccine
  - Only recently approved as childhood vaccine; now subject to VICP and VFC

Illustration of a Problem: Flu Vaccine Shortage 2004-2005

- Two flu vaccine manufacturers supplied US market
- One manufacturer could not deliver due to manufacturing problems
- Remaining manufacturer reallocated supplies
- Lawsuit against remaining manufacturer for reallocation
- "Price gouging"
  - Prices were set at 10x multiples of normal price
  - Prosecutions in Kansas and Florida
  - Not an FTC matter
- Mild flu season occurred, overall

Pandemic Flu Vaccine

- Reappearance of H5N1 (first appeared in 1997; re-appeared in 2003)
- NIH develops H5N1 vaccine
  - Vaccine requires high dosage, 6x normal amount of antigen (and 2 doses)
- Liability issues
  - New vaccine with pandemic potential; manufacturers' concern over liability
  - Health care workers concerned about liability for administration
- Flu budget supplemental and PREP Act
  - Development of Manufacturing Base and Capacity for both Egg-Based and Cell-Based Vaccine Production
  - Development of Antigen Sparing Techniques
  - Accelerate Cell-Based Vaccine
  - Development of Broad-Spectrum Influenza Vaccines
  - Expand Clinical Trials Infrastructure
  - PREP Act: Protection from Litigation

PREP Act: What it Provides

- Public Readiness and Emergency Preparedness Act:
  - **Covered person immune from suit and liability under federal and state law with respect to all claims for loss from administration of covered countermeasure**
  - **Loss is broadly defined, includes fear of injury and property loss**
  - **Administration includes manufacture, design, development, donation, prescribing, etc.**
  - **Administration must be under cover of a declaration**
  - **Declaration to specify disease, period or periods of effect, population of individuals, geographic area covered and possibly, means of distribution**
  - **State law preempted**
  - **Willful misconduct necessary to overcome immunity to suit and liability**

Federal Role in Pandemics: More Than Vaccines

- Surveillance
- Communication
- Support for development and production of medical countermeasures
- Support for planning
- Modes of prophylaxis distribution – not focused on vaccines
  - MedKit study underway in St. Louis
  - TopOff 3 and the role of State PODs